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#10
10-17-03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Customer No. 23643
Group: 2632
Confirmation No.: 5909
Application No.: 09/933,502
Invention: MEDICAL GAS ALARM SYSTEM
Inventor: Edward W. Catton et al.
Filed: August 20, 2001
Attorney
Docket: 7175-68263
Examiner: Crosland, Donnie L.

Certificate Under 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

on September 23, 2003

(Signature)

Karen Taylor
(Printed Name)

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SEP 29 2003

Technology Center 2600

DECLARATION UNDER 37 C.F.R. § 1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Edward W. Catton, a citizen of the United States of America and resident of New Palastine, Indiana, do declare and say that:

I am a joint inventor of the above-captioned patent application filed August 20, 2001. I understand that the Examiner has made a rejection under 35 U.S.C. § 103(a) of claims 1-139 of the above-captioned application based on U.S. Patent No. 6,421,571 to Spriggs et al., which was filed February 29, 2000 and which published July 16, 2002, and U.S. Patent Application Publication No. 2002/0020444 A1 to Dickerson, JR et al., which was filed April 6, 2001, which published February 21, 2002, and which is a continuation-in-part of application No. 09/248,328, filed on February 9, 1999, now abandoned, which is a

continuation of application No. 08/810,575, filed on March 3, 1997, now U.S. Patent No. 5,868,162.

Although, U.S. Patent Application Publication No. 2002/0020444 A1 claims priority as a continuation-in-part application to U.S. Patent No. 5,868,162, the portion of U.S. Patent Application Publication No. 2002/0020444 A1 referenced in the Office Action mailed June 27, 2003 to teach "monitored gas data over a network of computers" is page 10, col. 2, paragraph 124. This paragraph 124 did not appear in U.S. Patent No. 5,868,162. Therefore, the earliest effective date for the portion of U.S. Patent Application Publication No. 2002/0020444 A1 relied upon by the Examiner in making the rejection of claims 1-139 is April 6, 2001.

The conception of the Medical Gas Alarm System, which is shown and described in the above-captioned application and to which the claims of the above-captioned application are directed, occurred before February 29, 2000 as evidenced by the document titled "Sensor Powered Communication System Proposal" and accompanying hand sketch attached hereto as Exhibit 1. The documents in Exhibit 1 were created before February 29, 2000 and clearly show conception of a network connected Medical Gas Alarm System before the effective dates of each of U.S. Patent No. 6,421,571 and U.S. Patent Application Publication No. 2002/0020444 A1.

An actual reduction to practice of the Medical Gas Alarm System, which is shown and described in the above-captioned application and to which the claims of the above-captioned application are directed, occurred before April 6, 2001 as evidenced by the "Alarm Project-Prototype Review Meeting & Agenda" attached hereto as Exhibit 2 and by the "Preliminary Design Review Meeting Minutes" attached hereto as Exhibit 3. Exhibits 2 and 3 discuss a prototype system that was evaluated before April 6, 2001. The Issues Log beginning on page 2 of Exhibit 3 has main headings for Transducer, Area Module, Master Alarm, and Master Alarm-Web Page. Thus, an actual reduction to practice occurred before the effective date of U.S. Patent Application Publication No. 2002/0020444 A1. The prototype system included each of the limitations claimed in each of the independent claims of the above-identified application.

The reduction to practice of the Medical Gas Alarm System, which is shown and described in the above-captioned application and to which the claims of the above-captioned application are directed, was undertaken in a diligent manner after conception. Many activities took place after conception and leading up to the reduction to practice, including but not limited to the following activities:

1. Determining the requirements for the proposed Medical Gas Alarm System to obtain Underwriter's Laboratory (UL) approval, Canadian Standards Association (CSA) approval, and European Community approval (CE).
2. Formulating the initial design specifications document.
3. Creating non-working concept models.
4. Presenting, on a confidential basis, the concept models to focus groups to confirm the viability of the various functions proposed to be included in the Medical Gas Alarm System.
5. Designing the physical structures to house the master alarms, area alarms, transducer modules, and local alarms.
6. Designing the circuitry to accomplish the functions proposed to be included in the master alarms, area alarms, transducer modules, and local alarms.
7. Writing the software code that governs the operation of the circuitry of the master alarms, area alarms, and transducer modules.
8. Designing the web pages of the web sites hosted by the master alarms and area alarms.
9. Identifying potential components suppliers for the multitude of components included in the master alarms, area alarms, transducer modules and local alarms.

10. Obtaining price quotes from the various components suppliers of the parts to potentially be supplied by such suppliers for creation of a prototype system.
11. Obtaining from the suppliers the parts necessary to build the prototype system.
12. Refining the formal design specifications during the design process. See, for example, the "Medical Gas Alarm Marketing Specification" which is attached hereto as Exhibit 4 and which was created prior to February 29, 2000.
13. Performing cost and business analyses to confirm the viability and competitiveness of the proposed Medical Gas Alarm System.
14. Receiving the ordered parts from the various component suppliers.
15. Assembling the parts to create the prototype system.

The process undertaken by the inventors in reducing to practice the Medical Gas Alarm System was in accordance with the standard concept development procedures and new product development procedures of the assignee of the above-captioned patent application. As is evidenced by the large number of drawing sheets (i.e., 180 drawing sheets) in the above-captioned application, the majority of which are circuit schematics of the Medical Gas Alarm System, this system is a very complex system which required a vast number of man hours to reduce to practice after conception.

Attached as Exhibit 5 is a packet that was submitted as an Appendix C to a report titled "MEDICAL GAS ALARM PROJECT, GATE ZERO APPROVAL" which was made to top level managers of the assignee in order to obtain approval for funding to move out of the concept development stage into the new product development stage. Exhibit 5 includes a document saved under the name "legend.doc" which, on information and belief (based on computer records from inventor James P. Hentges), was created before the effective dates of each of U.S. Patent No. 6,421,571 and U.S. Patent Application Serial No. 2002/0020444 A1. Exhibit 5 also has a set of digital photos of the non-working concept models that were created prior to the effective date of each of U.S. Patent No. 6,421,571 and U.S. Patent Application Serial No. 2002/0020444 A1.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, or any patent issuing thereon.

Dated: 9/17/03

By: Edward W. Catton
Edward W. Catton

EXHIBIT 1

L. Robert Kylo

Sensor Powered Communication System Proposal

Date: , revised

Author: L. R. Kylo, Research & Design, Inc., (507) 454-7923

Overview:

A structure has been devised that allows remarkable flexibility and integrity of a sensor system. The basic component is the *transducer module*, which senses a parameter and relays the information, by *telemetry*, to a maximum of five *display modules*. The display modules serve to monitor the telemetry, transmit data, and check data against either default values transmitted by the transducer module, or against a value set by an associated supervisory module called a *Master Unit*. These supervisory modules may be networked via their associated sensor grid.

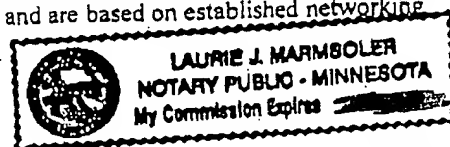
The smallest organizational form is the *transducer group*, formed when a transducer monitoring a particular parameter, and a display module, are connected. Up to five display modules may be connected to one transducer, any one of which can supply power to the transducer. If one display module is removed there is no effect on sensor telemetry to the remaining modules. If a new module is connected, and power applied, it will begin to monitor the telemetry data and automatically log in to the transducer group. No *intervention* is required to *configure* the attached devices and they are designed to be *hot plugged*.

Display modules do more than only monitor transducer telemetry and display the data. Based on timing received from the transducer module telemetry, it is allowed a *time slot* to transmit to all the other display modules associated with that transducer. If one, some, or all of the display modules of the transducer group are *associated* with a master unit then those master units can communicate to the display modules any change in settings, or change parameters, or request additional data. Since all the display modules on a transducer module share information with each other this provides a means of constructing a small or large *network* communicating via associated transducer groups. (See attached diagram.) Display modules connected to a transducer module respond to commanded changes in a last-orders-first sequence, ensuring they hold the most recent information. They also are capable of passing *data packets* to other display modules of the transducer group which may be connected to master units.

Master units provide a focus for monitoring associated display modules to which up to nine may be connected. Switch closures may also be monitored, with up to 100 or more switch inputs either directly or via a *switch module*. Master units also provide the entry point for changing settings on transducers or entering information to share with the network at large. A computer may be connected to the Master unit and information entered for network distribution via the Master module, and providing systems management.

The Master units, display modules, and transducer modules may be interconnected as a network so that Master units are linked to other Master units via common transducer groups. Variables may be set or changed in specific transducer groups or all transducer groups of the same measurement type from any master (assuming proper security precautions,) via this network. Instructions may be issued from one point on the network to be executed on another. Special *communication link modules* provide a "bridge" among up to five display modules to connect portions of the network that would otherwise be detached. As with any transducer group this allows a communications within a transducer group to transfer data at distances of up to 4.7 kilometers (~1.9 miles), providing a means of connecting separate buildings and *clusters* of master units in remote locations. This network would be *self configuring* and require no intervention to begin operation.

Details of the transducer group log in procedure, data interchange, *network protocol*, and *discontinuity management* are detailed elsewhere and are based on established networking



Laurie J. Marmoleo

L. Robert Kylls

principles. For those not familiar with the technical terms, a glossary of *italicized* words is provided to help understand the system.

Glossary:

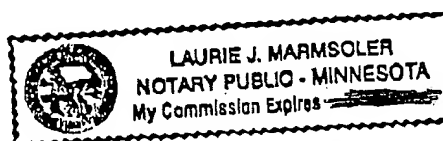
Definitions as used in this document:

- *Association*; An assemblage of units connected to common elements in some manner.
 - *Cluster*; An assemblage of master units associated with the network by a single line of communication.
 - *Communication link module*; a special form of transducer module which has the exclusive purpose of facilitating communication among display modules
 - *Configure*; the process of acquainting components of a network how, and to what, they are connected.
 - *Data packets*; short sequences of information that are passed among elements of a network that may or may not be used by the element handling it.
 - *Discontinuity management*; a set of rules for orderly handling non-critical (not relating to the primary measurement) connection or network related problems.
 - *Display module*; a module containing all the features needed to provide power and monitor a sensor transducer module. Additionally it communicates among other display modules in a transducer group and with its associated master unit.
 - *Hot plug*; A feature of the network elements that allow connection or disconnection while the rest of the system continues to function normally.
 - *Intervention*; The requirement for a manual operation to maintain the function of an element of the entire system when a change is introduced.
 - *Master unit*; An element of the system that connects to switch inputs, display modules, and computers. It provides a point for entry or reading of data obtained from a sensor or the network.
 - *Network protocol*; The rules that allow a network to function properly.
 - *Network*; The total assemblage of elements all in communication with each other to facilitate orderly and compliant system functioning.
 - *Self configuring*; A means of inserting and withdrawing elements of a transducer group or network without manual intervention.
 - *Switch module*; A module that reads switch inputs and interfaces to a Master Unit.
 - *Telemetry*; From Greek which means "Far Measure" and now generically means to send data about some process or measurement to or from a remote location, the distance being relative.
 - *Time slot*; An element of communications protocol that assigns a device a defined time in sequence for a particular purpose, usually communication. It is part of the "Modified Aloha Protocol," a subset of which is used by the system.
 - *Transducer group*; All of the display modules that are connected to a particular sensor transducer module.
 - *Transducer module*; The module that physically senses a quantity and via telemetry communicates it to the display modules connected to it. It also provides the sequencing for display modules to obtain a time slot for communication among the transducer group.
- Transducer modules receive power from one to five display modules.

L. Robert Kylls

Aug 5 1977

Bob Marmar



Laurie J. Marmar

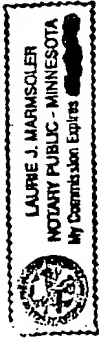
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PAGE. 02

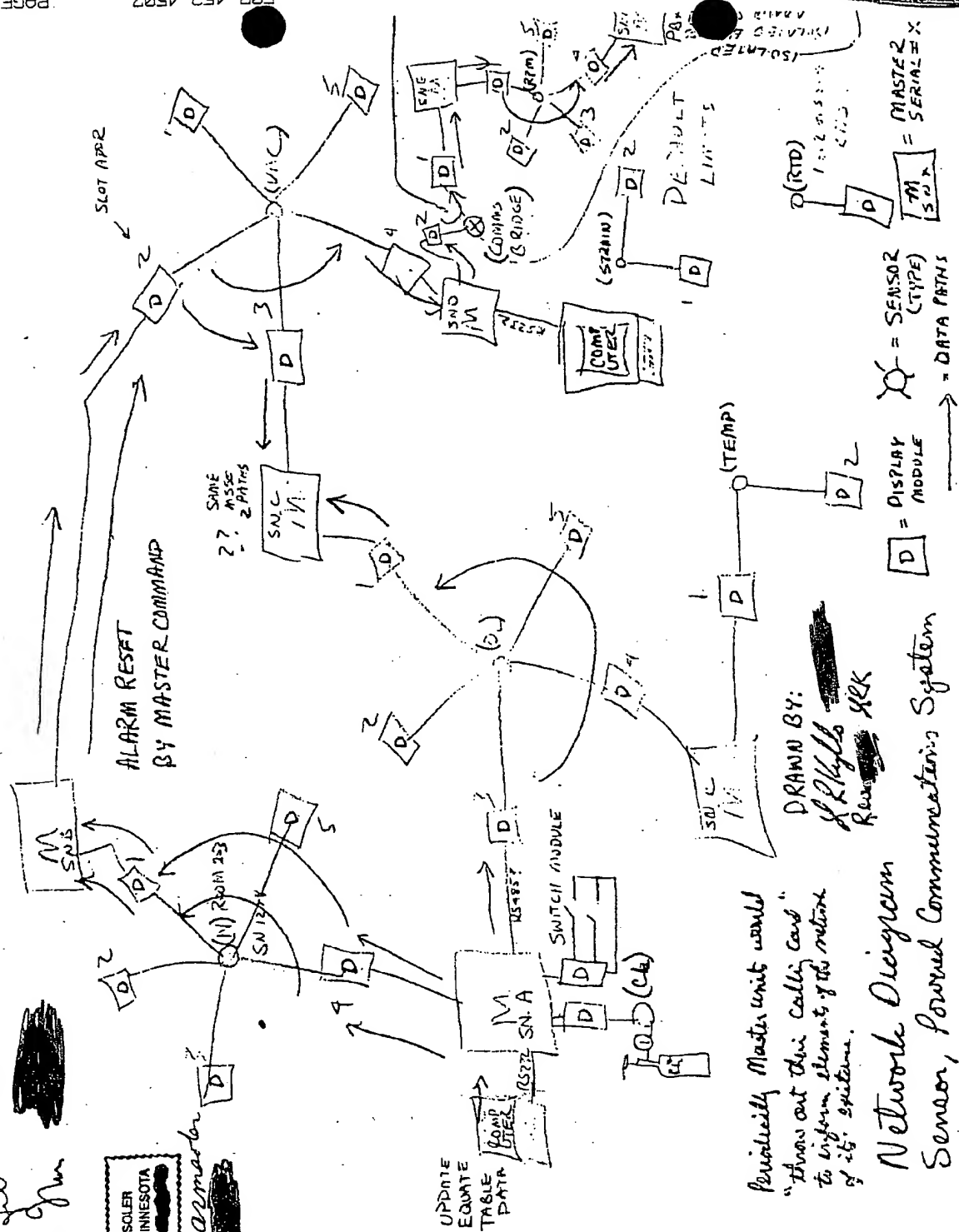
Robert Kyll

David Jell

Bob Jim



Laurie J. Marmosier



Periodically Master unit would "throw out this calling card" to inform elements of the network of its existence.

Network Diagram
Sensor, Power Communication System

EXHIBIT 2

ALARM PROJECT - PROTOYPE REVIEW MEETING & AGENDA

The Medical Gas Group is currently developing a new Medical Gas Alarm. Product Launch is scheduled for year end [REDACTED]. This prototype meeting will evaluate the products for compliance to their respected specifications. Prototypes will be available for the Master Alarm Panel, Area Alarm Panel, Transducer and the Comm's Unit. The Test Simulator prototype will be reviewed at a later date. Our goal is to approve the product design (with or without changes) so we can finalize design and continue along the project schedule.

Participants:

Jim Hentges, Project Manager (Watlow)
Bill Bohlinger, Electric Design (Watlow)
Stan Breitlow, Software (Watlow)
Chuck Murphy, Sales (Watlow)
Don Andersen, Director
Bill Kaht, Marketing Manager
Ed Catton, Project Manager
Joe Abel, Mechanical Design
Jack Wilker Sr., Electrical Design
Jerry Batta, Regulatory
Rose-Ann Heath, Test Lab Manager
Dick Hoffman, Consultant
Craig Williams, Medical Pipeline Specialist

ADGENDA

Meeting Location: The "AP Kaizen Room" is reserved for Tuesday and Wednesday.

Monday [REDACTED]

- 2:00 p.m. Tour of Hill-Rom

Tuesday [REDACTED]

- 7:30 a.m. Kick-Off and Refreshments
- 8:00 a.m. Prototype Review to Specifications
- 11:30 a.m. Lunch (all participants)
- 1:00 p.m. continue Prototype Review

Wednesday [REDACTED]

- 8:00 a.m. Initial Risk Assessment – to identify potential risk or hazards associated with the product and its environment.
- 11:30 a.m. Lunch and Departure

Any questions, please let me know.

Thanks,

Ed Catton

EXHIBIT 3

Preliminary Design Review Meeting Minutes

PROJECT: ALARM PROJECT

Distribution: Design History File
Project Leader

Written By: Ed Catton

 Date: 

[Project Leader]

Meeting Date and Time:  7:30 a.m. -- 4:00 p.m.

Attendees:

Name	Company	Role
Rose-Ann Heath	Hill-Rom	Test Specialist
Jack Wilker Sr.	Hill-Rom	Lead Engineer
Bill Kaht	Hill-Rom	Marketing/Sales Specialist
NA -- later design review		Manufacturing Specialist
Jerry Batta	Hill-Rom	Regulatory Specialist
Craig Williams	Hill-Rom	Service Specialist
Dick Hoffman	Hoffman and Assoc.	Outside Reviewer
Don Andersen	Hill-Rom	Med Gas Director

* Priority Legend

A = Safety issue that can cause death or injury if not corrected.

B = Condition not involving safety that results in the device not meeting specification.

C = Non-conforming condition that results in a minor nuisance to the user.
D = An observation that does not fit into A, B, or C.

Joe Abel	Hill-Rom	Designer
Jim Hentges	Watlow	Project Manager
Chuck Murphy	Watlow	Sales
Bill Bohlinger	Watlow	Electrical Design
Stan Breitlow	Watlow	Software Design
Dan Rogers	Hill-Rom	Test Lab -- Electrical
Dave Bauereis	Hill-Rom	Test Lab - Software

Issues Log

ID #	Priority (A - D) *	Date of Occurrence	Requirement or Issue Description	Responsible Party	Resolution Imp. Date	Resolution/Mitigation Strategy
1	D		Test equipment needs attention sooner than later.	HR / Watlow		
2	D		Technical Documentation needs to be started now during the design stage. (installation instructions)	Kaht / Catton		
3	D		Watlow's documentation shall have HR proprietary info.	Jim Hentges / Joe Abel		
4	D		UL 1069 states 8 kV for ESD, Watlow to test to 15 kV.	Jim Hentges		
			Transducer			
5	A		Pipe thread OK to brass nut on transducer. Watlow to install DISS fitting. Hill-Rom to supply Watlow.	Jim Hentges		
6	C		Watlow to test DISS fitting for leakage.	Watlow		
7	B		Transducer to be shipped in sealed bag for oxygen cleanliness.	Watlow		

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ID #	Priority (A - D) *	Date of Occurrence	Requirement or Issue Description	Responsible Party	Resolution Imp. Date	Resolution/Mitigation Strategy
8	D		Tamper proof sealant for DISS fitting around pipe threads.	Watlow		
9	D		Heart beat LED on transducer – should be green not red. 2 LED's OK.	Watlow		
10	D		Optional conduit (1/2 inch) mount in transducer housing. Similar to current transducer.	Nick Labare		
11	D		Transducer to support only one (1) area module not 2. Three pin terminal block.	Watlow		
12	B		Three-pin terminal block with ground terminal not terminating – on connected to earth ground. Terminals to be labeled, atleast ground terminal.	Nick Labare		
13	A		Plastic barrier or guard for pc board. Snap in design? Should not be readily to access pc board. Transducer will be not a serviceable item.	Nick Labare		
14	A		Terminal block to be exposed outside of plastic pc board barrier.	Nick Labare		
15	A		Provide additional support or ribbing under pc board especially under terminal block to protect board from breaking.	Nick Labare		
16	A		Provide mounting holes through pc board to allow screws to attach to brass nut. Provides more positive sealing.	Nick Labare		
17	A		Brass nut for DISS connection. Does not required plating. Does need to be Oxygen Cleaned .	Nick Labare		
18	A		O-ring shall be Viton material.	Nick Labare		

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Rev. 1

ID #	Priority (A - D)*	Date of Occurrence	Requirement or Issue Description	Responsible Party	Resolution Imp. Date	Resolution/Mitigation Strategy
19	A		2% accuracy over operating pressure range.	Watlow		
20	A		Plastic enclosure shall be rated UL V-O smoke rating.	Nick Labare		
21	C		Strain relief for wire - Heyco type fitting or instructions to tie knot in wire. Also instructions to wire tie cable to secure structure to prevent wire from pulling out of terminal block.	Nick Labare / HR		
22	D		Specs for accuracy and leakage.			
23	D		No mounting tabs required on transducer enclosure.	Nick Labare		
			Area Module			
24	D		Possible longer housing or two boards to recess boards in housing. Better protection of boards.	Watlow		
25	D		Wire connection straight out of back to module.	Watlow		
26	B		Break out board to attach field wiring during rough-in stage. This provides control and positioning of cables by Hill-Rom due to hinged Area Alarm cover panel.	Watlow		
27	B		Units of measure (kPa, psi) shall be factory set because label specifies kPa or psi. Also different color coding for kPa (ISO) labels.	Watlow		
28	D		Move units of measure (psi) on overlay closer to numeric reading on display like concept models.	Nick Labare		
29	B		Must be capable of reading low and high pressure set point. Use up and down arrow.	Watlow		
30	C		Alarm audible repeat optional. No repeat, 30, 60 or 120 minutes.	Watlow		

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ID #	Priority (A - D) *	Date of Occurrence	Requirement or Issue Description	Responsible Party	Resolution Imp. Date	Resolution/Mitigation Strategy
31	D	REDACTED	Error message - alarm and flash.	Watlow		
32	B	REDACTED	Alarms and error codes use same alarm routine, sound audible, silence option, and flash message.	Watlow		
33	C	REDACTED	No flashing or audible alarm during start-up mode.	Watlow		
34	B	REDACTED	Two relay output signals, one to mimic normal alarm activity and one to stay on when an alarm is present.	Watlow		
35	B	REDACTED	Green LED needs to be brighter then proto.	Watlow		
36	D	REDACTED	Transformer provided by Hill-Rom - thermal resettable instead of separate fuse - Jack to investigate.	Abel / Wilker		
37	A	REDACTED	Switch for power off on transformer housing.	Abel / Wilker		
38	A	REDACTED	AC power barrier to separate from low voltage.	Abel / Wilker		
39	A	REDACTED	Wiring hook-up label in rough-in box.	Abel / Wilker		
40	D	REDACTED	Connector board with and with out communications option.	Watlow		
41	B	REDACTED	Label area under each area module for customer to designate area of monitoring.	Abel / Catton		
42	D	REDACTED	Blank area module. New tool required for Watlow.	Watlow		
43	D	REDACTED	Connector board shall have ribbon cable vs. RJ 45 connector.	Watlow		
44	D	REDACTED	(3) module cover panel and (6) module cover panel.	Abel / Catton		
			Master Alarm			

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Rev. 1

ID #	Priority (A - D) *	Date of Occurrence	Requirement or Issue Description	Responsible Party	Resolution Imp. Date	Resolution/Mitigation Strategy
45	D		Area message going to Master Alarm must be changed by <u> </u> . The <u> </u> (detailed message) over rides the Area Module description.			
46	D		Comm's unit independent of Master Alarm.	Watlow		
47	C		What happens when an Area Module is off line or shut down?	Watlow		
48	D		What needs to be done if an Area Module is taken out indefinitely? "Clear Network"	Watlow		
49	D		No flashing or audible alarm during set-up mode.	Watlow		
50	D		Review Configuration of Master Alarm.	Watlow / Kaht		
51	D		Manual should have set-up work sheet for Configuration.	Kaht / Tech. Doc.		
52	D		Pager / E-mail option.	Watlow		
53	A		Message scroll too fast.	Watlow		
54	A		Each error needs to audible alarm when multiple alarms come in.	Watlow		
55	A		Gas type LED shall flash red to indication alarm message waiting. Helpful if multiple alarms at one time.	Watlow		
56	B		Audible alarm optional - off, repeat 30 minutes or 60 minutes.	Watlow		
57	B		Breakout board for field wiring termination during rough-in stage.	Watlow		
58	A		1 amp 30 V auxiliary relay for remote audible alarm.	Watlow		

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Rev. 1

ID #	Priority (A - D) *	Date of Occurrence	Requirement or Issue Description	Responsible Party	Resolution Imp. Date	Resolution/Mitigation Strategy
59	D		Transformer same type as used in Area Alarm.	Abel / Wilker		
60	A		Barrier housing for transformer.	Abel / Wilker		
61	A		Transformer shall have a shut-off switch.	Abel / Wilker		
62	A		Tool required to open Master Alarm Panel.	Abel / Catton		
63	B		N2 connector for building automation.	Watlow		
64	A		Guarded access from back of Master Alarm Panel for config. Set-up.	Watlow		
65	D		Nema 1 type rough-in box. Preferably same box as Area Alarm.	Abel / Catton		
66	A		Wiring hook-up label in rough-in box.	Abel / Wilker		
67	B		Overlay with embedded LED's and switches shall be removable for replacement.	Watlow		
68	A		In addition to test sequence, add alarm config information.	Watlow		
69	A		Audible alarm if bad micro.	Watlow		
70	D		Plastic bezel for overlay or plate mount.	Watlow / HR		
			Master Alarm - Web Page			
71	D		Message Label for _____ and system status.	Watlow		
72	D		System config can be printed from PC after certification.	Watlow		
73	D		No Alarms Active status - Time / Date added	Watlow		
74	D		Log event when down load log and who down loaded.	Watlow		

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ID #	Priority (A - D) *	Date of Occurrence	Requirement or Issue Description	Responsible Party	Resolution Imp. Date	Resolution/Mitigation Strategy
75	D		Device location description – only 20 characters.	Watlow		
76	D		For Area Alarm location title – Zone or Area	Watlow		
			Test Simulator			
77	D		Not pursuing at this time. Only good to check electronics.	HR		

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EXHIBIT 4

CONFIDENTIAL
Hill-Rom
PIPED MEDICAL GAS AND VACUUM ALARM SYSTEM
Design Input/Marketing Specification – Product Assessment
[REDACTED]

*Exhibit A
Replacement
SR/PH*

1. Terms and Documents

1.1 Scope

This specification describes requirements for intended use and customer needs of piped Medical Gas and Vacuum Alarms for Health Care Facilities.

1.2 Non-Standard Terms

1.3 Acronyms

1.4 Governing Documents

Governing documents include:

- NFPA 99 "Standard for Health Care Facilities" (1999)
- CSA Z 305.1-M1984 "Nonflammable Medical Gas Piping Systems"
- Watlow Product Requirements Documents

2. General Description

2.1 Concept

Medical Gas Alarms are required by NFPA and CSA Codes to continuously monitor the status of all piped medical gas and vacuum systems. Alarm panels containing audible and visual indicators for required and optional signal conditions are located at various points throughout the health care facility where there is continuous surveillance and the need to know medical gas and vacuum systems are operating properly. Should a monitored condition fault occur, an audible and visual signal is activated on the alarm panel to alert the need for necessary action.

This alarm system will utilize state-of-the-art electronic technology to create a basic platform to provide all required signals necessary to monitor piped systems in a typical health care facility. Construction will be modular for both ease of installation and facility service/repair. Alarm system modules will be configured into "Master Panels" that monitor system source conditions and "Area Panels" that monitor systems in specific patient care areas within the facility. In cases where a local alarm is required, the Master Alarm panel shall be used to meet these requirements. Optional capability to communicate system conditions from Area to Master Panels by specific location will be accommodated without the need for separate computer functions. The Alarm system will be capable of communicating with conventional building automation systems via a standard interface. Software will be made available to configure the alarm system to a specific facility.

2.2 Intended Users

Alarms are intended for operating, maintenance and patient care providers within the health care facility who are responsible for proper operation of medical gas and vacuum

systems or who use piped medical gas and vacuum services in the care and treatment of patients.

2.2.1 Intended User Requirements

1. Alarm signal must be easily identified both as to the specific fault condition and the gas/vacuum system effected.
2. The audible fault signal must be capable of being silenced.
3. The visual fault signal must remain activated until the condition is corrected.
4. A "system normal" visual indicator must be present to indicate that all monitored systems are normal and the alarm itself is functioning properly, including the field wiring and sensors.
5. All the necessary signals should be accommodated in a single panel sized for as small a wall surface area profile as possible.
6. There must be a "test" function on each panel or module to check audible and visual indicators and alarm system operation.
7. An actual pressure or vacuum reading of each monitored service must be provided at each panel.
8. High and low pressure/vacuum alarm set points must be adjustable up to system pressures of 200 psig or vacuum to 30" Hg; to tailor the alarm for special applications such as hyperbaric chamber piping.
9. User operated switches shall have a tactile feel.

2.3 Product Claims

- Reliable (Designed for 25 year operating life)
- Easy to install (Twisted pair field wiring, up to 5000 feet per signal line and "Star" interconnect option between panels. No polarity (may be interchanged).
- Easy to configure (Supplied preprogrammed for basic signals and values as stated in current NFPA 99 and CSA Z305.1 Codes).
- Easy to re-configure (Adjustable set points and available Facility Specific software)
- Communicates with building automation systems via RS 232 serial port interface.
- Low susceptibility to EMI/RFI interference (ref. IEC 601-2)
- Low EMI/RFI output (ref. IEC 601-2)
- Not damaged by supply power line voltage and current "spikes" and transfer to emergency power, having a 60 second maximum hold time.
- UL, CSA and EC design certified.

2.3.1 Technical Specifics

- Transducers shall meet standing pressure test requirements of NFPA and CSA.
- Conformal coated circuit boards.
- Batch or date codes or other method of traceability.
- Transducers components touching gas stream shall be cleaned for O₂ use.
- Eight bit resolution.
- Transducers shall be rated for 200 psi for area alarm pressure gases, 3000 psi for master pressure gases and 30"Hg for vacuum .
- Accuracy of systems to be greater than or equal to 2% of readings (non adjustable in field by user).

- Transducers to have color coded label to match encoding and DISS connector.
- Wiring connections to be made with a terminal block with minimum #6 screws with barriers.
- Test simulator available for field testing during installation to simulate transducer signals and to read and verify transducer information.

2.4 Model Variability

2.4.1 Base Configurations

General – kPa or PSI must be displayed to indicate actual units mode of alarm. Telephone modem.

Master Alarm Panels – Accommodate up to 9 piped services with up to 14 signals each (126 signals). Fault conditions are visually indicated via emissive type display and text message in conjunction with LED system status indicator.

Area Alarm Panels – Accommodate up to 6 piped services with up to 3 signals each. May be modular with individual panels capable of supporting up to 3 and up to 6 modules. Actual system pressure or vacuum is continuously displayed in the desired English or Metric units for each monitored system.

Local Alarm Panels – Accommodate up to 4 service systems with up to 10 signals each (40 signals). Master Panels may be configured to meet this need.

Pressure/Vacuum Transducers – Service specific for each system and individually electronic serialized capable of transmitting pressure or vacuum system values up to three locations. Must be gas specific using DISS connections to the piping system. Must be capable of 200psi or 30"Hg for Area alarms and 3000psi or 30"Hg for Master.

2.4.2 Options

- Computer Interface for communications with Building Automation System.
- Time/date signal log.
- English, French, German and Spanish.
- Fault Signal acknowledgment.
- Facility specific configuration software

2.4.3 Accessories

- Integration with gas control centers.

3. Requirements

Meet NFPA 99 and CSA Z305.1 Requirements

3.1 Customer Requirements

- 3.1 Alarm Panels should be packaged to protect them from physical damage, dirt, dust, moisture and construction debris typical at new construction job sites.

1. Packaging should anticipate two phases of installation: A rough-in phase, before the walls are closed to locate the panel and run field wiring and a finish phase after the walls are closed to trim the panel and complete the installation. On Master alarms, this includes connecting the sensor wires to a terminal strip on a break-out board that is part of the rough-in box that connects to the front panel electronics via a multi-conductor cable and connector. This shall allow the wiring to be completed prior to the installation of the alarm panel and the alarm panel to be removed for service without disconnecting the individual service wires.
2. The Alarm systems should be designed for ease of installation, including twisted pair field wiring and inter-panel connections. All wiring terminals must be clearly identified and wiring connection hardware easy to manipulate.
3. Must have the capability to furnish job specific wiring diagrams if necessary.
4. Alarm Panels should accommodate a variation in wall thickness from 3/8" to 1 1/4" and trim the rough wall opening by not less than 1/4".
5. Alarms must provide for all required signals per NFPA 99 and Z305.1 at Master and Area Panels.
6. Alarm Panels should accommodate the following gas/vacuum systems and identify associated signal with North American and International color-coded labeling:
 - OXYGEN
 - MEDICAL AIR
 - VACUUM
 - WAGD (AGSS for ISO)
 - NITROUS OXIDE
 - NITROGEN
 - CARBON DIOXIDE
 - HELIUM
7. Terminal connections shall be with screws no smaller than #6.
8. All visual marking and indicators must be readable at a distance of one meter with 20/20 vision and background lighting at 215 lux.
9. Alarm System Area and Master Panels and Transducers shall conform to the Product Configuration Matrix.
10. Alarm System shall be capable of interfacing with building management systems as required. (RS 232 port).
11. Alarm shall utilize component modular design for ease of configuration, service replacement, future revisions without the need for special tools or to alter internal wiring.
12. Alarms shall be manufactured by an ISO 9000 certified supplier.
13. All alarms to be labeled for specific location per NFPA and CSA.
14. All parts to be labeled with Hill-Rom part numbers.

3.2 Performance Requirements

1. Alarm Panels shall produce an audible and visual signal whenever the system pressure increases 20% or decreases 20% from normal setting or when the system vacuum level falls below 12 inches of mercury. These alarm set points shall be capable of field adjustment as may be required for individual systems.

2. The audible signal shall be a minimum of 80 dBA at one meter and able to be cancelled. Additional fault signals shall reactivate the audible signal.
3. The visual signal shall not be cancelable until the fault is corrected and shall automatically reset.
4. Alarm panels shall provide a reading of actual system pressure or vacuum.
5. All signals shall be clearly identified and associated with the piped gas or vacuum systems they originate from.
6. Method available to easily restore to default settings.

3.3 Reliability Requirements

1. All fault signals shall originate upon interruption of a normally closed, supervised circuit.
2. Transducer signals shall operate in a closed loop circuit. Any interruption, break or short circuit of the wiring shall be indicated as an alarm system fault on the corresponding display(s).
3. Alarm system shall operate at low voltage (24V AC) from both the normal and emergency facility 115/120 VAC +/- 10% 50/60 Hz electrical power systems.
4. Alarm Panels shall be self-monitoring with "system normal" indicator showing when no fault conditions are present and serves to advise that the Alarm system itself has no faults.
5. Any test function shall check integrity of system and field wiring.
6. Alarm system faults shall be indicated by a code to identify the nature of the fault (i.e. F-1 = Transducer not functioning).
7. Alarm system shall not malfunction due to EMI/RFI interference or emit excessive EMI/RFT signals (ref. IEC 601).
8. Alarms shall be designed for low maintenance such as replacement of visual indicators, components, etc.
9. Components and assemblies shall not be damaged when subjected to an ESD of 15 KV air, 8 KV contact.
10. Supervised circuit detects either open or shorted connection.

4. Physical Attributes

4.1 General Physical Characteristics

1. Metal rough-in box must fit within standard 4" nominal wall and accommodate a variation in finished wall thickness up to 1 1/4" and a maximum 1/4" finish gap.
2. Minimize surface wall area.
3. Area Alarm individual signal modules shall be capable on integration with other Hill-Rom products, such as headwalls and gas control centers.
4. Attractive design décor consistent with health care facilities.
5. Alarms shall be durable and resistant to damage when cleaned using common cleaning and disinfectant materials and have an aesthetically pleasing appearance (Hill-Rom specification M020004.02)
6. Alarm Panel mounting boxes shall be equivalent to 18 gage metal and have a oxidizing protective coating if necessary.
7. Exterior surfaces of Alarm Panels shall be non-oxidizing and resistant, including markings, to wipe cleaning with commonly used chemicals and disinfectants.

4.2 Overall Dimensions

1. To be determined. A small profile and wall surface area is desired.

4.3 Weight Requirements

1. Weight should be kept to a minimum.

4.4 Color or Texture Requirements

1. Color and texture should be selected to blend with common finished wall treatments having smooth rounded surfaces (few ledges) and easily wiped clean.

5. Performance

5.1 Product Operational Requirements

1. Provide separate visual indicators for each system and condition monitored.
 2. Provide cancelable audible indication of an alarmed fault condition producing a minimum of 80 dBA sound at 1 meter.
 3. Additional fault conditions occurring while the alarm is silenced shall reinitiate a new audible and visual signal while retaining all previous fault signals.
 4. Provide both visual and audible signals when a monitored fault condition occurs.
 5. Provide visual and audible signals when wiring to the sensor or switch is disconnected or interrupted and when there is an alarm component failure interrupting system monitoring capability.
 6. Provide labeling surface for the area of Alarm Panel surveillance (i.e. room #'s) and piped service monitored (oxygen, vacuum, etc.)
 7. Master Alarms
 - a. Shall monitor the operation and condition of the piped service (gas/vacuum) source of supply, the reserve supply (if any), and the pressure of the main line serving the facility.
 - b. Shall consist of two or more Panels that are located in separate locations to assure continuous surveillance during working hours of the facility. One location is usually the working area of the individual responsible for maintenance of medical gas and vacuum systems.
 - c. Shall include pre-programmed audible and visual signals for:
 - Gas system supply changeover from operating to reserve supply
 - Gas system supply changeover for normal to an emergency reserve supply
 - Emergency Gas reserve supply low
 - Cryogenic gas reserve pressure low
-
- A change of +/- 20% from normal gas system pressure in the main line serving the facility.
 - Medical Air Compressor System Fault Indicator
 - Vacuum Pump System Fault Indicator
 - Medical Air dew point high
 - Medical Air carbon monoxide alert

- Reserve Compressor running
- Reserve Vacuum Pump running
- Accept up to a maximum of 675 additional signals to be determined by the facility.

8. Area Alarms

- a. Shall monitor piped systems supplying: anesthetizing locations, vital life support and critical care areas, intensive and coronary care units and are usually located at the nurses station or where there is responsible surveillance.
- b. Shall Indicate by an audible and visual signals when the pipeline pressure deviates +/- 20% from normal or when the piped vacuum system level drops below 12" Hg. Alarm set points in Area Panel modules are field adjustable for system pressures up to 200 psig and 30" Hg. vacuum.

9. Local Alarms (must be able to be handled by a Master alarm)

- a. Primarily associated with Vacuum and Medical Air sources (pumps and compressors) and are usually located in the room or area where these systems operate to monitor the operation of these systems and are capable of communicating fault conditions to the Master Alarm.
- b. Shall provide Medical Air Compressor and Vacuum Pump pre-programmed audible and visual signals when:
 - Backup compressor operating
 - High water level in receiver
 - High water level in separator (if applicable)
 - High discharge air temperature (if applicable)
 - High carbon monoxide level above 10 ppm
 - Backup vacuum pump is operating
 - Pressure dew point above 39°F. – also goes as a separate signal to the Master Panels.

5.2 Options - Operational Requirements

1. Signal Acknowledgement – When the audible signal is cancelled at any Alarm Panel that action is communicated to a central location confirming the signal was received and acknowledged via a time and date notation. Return acknowledgement is desired.
2. Time Recording – The time a particular fault signal was activated is recorded on a central computer and a log of system operation is documented for facility records. Gas system topology display of pressure over time displayed on a PC.
3. System Maintenance – Logs routine, scheduled and situation maintenance of piped medical gas and vacuum systems.
4. Auto-dial alert to appropriate personnel when there is a system fault.
5. The ability, using additional software, to facility customize the alarm system and communicate area fault conditions at the master panel(s) by specific system and location.
6. Remote access to Alarm system from telephone or modem.
7. Master Alarm to monitor vacuum pump and compressor systems for elapsed hours and signal when maintenance is due (as specified by user).

8. Regulatory/Safety

6.1 Government Documents

- Medical Gas Alarms are not classified as Medical Devices at this time in North America.

6.2 Industry Documents

- NFPA 99 (1999)
- CSA Z305.1
- IEC 601
- UL 1069, CSA Z22.2, 125

6.3 Hill-Rom® Documents

6.4 General Safety Requirements

9. Expected Product/Component Life

7.1 Expected Product Life

1. 25 years

7.2 Expected Component Life

1. 25 years

10. Environment

8.1 Storage, Shipping and Handling Requirements

1. -40°F. to +140°F
2. Electrostatic protection of sensitive components
3. Protection from construction contamination: water, dust, debris, etc.

8.2 Electrical Power Requirements

1. 105-140 VAC reduced to 24 V AC
2. Connected to facility emergency generator power supply

8.3 Operating Conditions Requirements

1. 35°F to +120°F, 10-90% rh

8.4 Cleaning Procedures Requirements

1. Commonly used cleaning and disinfectants in Health Care Facilities per Hill-Rom specification M020004.02.

11. Serviceability

9.1 Maintenance Requirements

1. Medical Gas Alarms should be designed not to require maintenance for the 25 year life of the products.
2. It will be necessary from time to time to change system alarm parameters and this should be accomplished with little effort or technical skills.

3. Alarm Panel relocation can be anticipated.
4. Exposed surface cleaning and disinfecting can be expected.

9.2 Service Requirements

1. Routine service should not be required during the life of the product.
2. Electronic component replacement is limited to board level assemblies
3. In-line transducers are replaceable.
4. Alarm Panels should incorporate a self-diagnostic capability with fault code display to indicate the nature and source of a problem.

EXHIBIT 5

**MEDICAL GAS ALARM PROJECT
GATE ZERO APPROVAL**



Appendix C

Watlow Proposal



Watlow Controls

ISO 9001



1241 Bundy Boulevard

P.O. Box 5580

Winona, MN 55987-5580

Phone: 507-454-5300

FAX: 507-452-4507

Hill - Rom / Watlow Medical Piped Gas System

Enclosed is information that supports the Watlow approach of the Medical Gas system outlined through several revisions of meetings between Hill -Rom and Watlow. All costing scenarios explained depict Watlow compared to the Medeas system without AIMS. To introduce the feature set that John Sharer has requested the following is the only requirement:

Each Area Display Module / Panel will need to be accompanied by one Area Communication Transmission (ACT™?) module. With this added feature, Hill - Rom will have acquired the most powerful Medical Gas Monitoring system available on the market.

The System:

Once the system is installed, local signals wired to Master Module, Transducers wired to Area Display Modules, and communications from Area Display Modules / Panels to Master Module have been connected - Sit back and relax!

Scenario 1: Local Oxygen fault signal present - Master module indicates Oxygen fault by illuminating red LED, sounding audible alarm, and displaying text message on screen " Local Oxygen Pressure Low / High."

Scenario 2: Area fault signal present - Master Module indicates fault by sounding audible alarm, and displaying text message of "Floor 5 - Room 1148 - East Wing." The related Area Display Module will indicate fault condition other than "normal", audible alarm shall be sounding, and four digit display shall read actual pressure / vacuum.

Additional Support Cost:

The Area Communication Transmission module will be part of the Hill - Rom "rough in assembly". Reference quotations in rear of packet for complete system pricing.

Amico Features:

Microprocessor based with an individual microprocessor on each module.

Up to 60 functions in a standard configuration.

LED Alarm lights utilized for long life.

Area Alarm Modules can be intermixed with Master Alarm Modules.

Maintenance mode for ease of trouble shooting.

Self diagnostic circuitry for added reliability.

Modules can be upgraded in the field to interface welcomed, RS to a building management system. accommodate.

Alarm buzzer in excess of 90 decibels.

All modules to be mounted on a hinged frame for easy accessibility.

Last alarm flashes, acknowledged alarm shows continuous RED signal.

Repeat alarm adjustable 10, 15, 30 minutes or off.

UL Listed and CSA approved.

Proposed System Features:

Microprocessor based, only one module required.

Amico system requires 6 modules to accommodate 60 functions. Proposed, only one (30 signal capability).

LED alarm lights, combined with informative text message.

Separate panel required, however Master module will display Area fault via text message.

No maintenance mode required. Text message will display exact location, and type of fault.

Self diagnostics including self configuring of system elements.

Building Automation systems
232 port available to

Audible alarm (90 decibels at 2 meters) NFPA states 80 decibels at 1 meter.

Proposed system to hinge open right to left rather than hinge down. Eliminating shorting opportunities.

Audible alarm, LED indication, and sequencing text messaging of alarm(s)

Repeat alarm adjustable in one minute increments. Default TBD.

U.L. / CSA / CE approved.

No gas labeling required.

Does not require additional hardware to deliver on screen text messaging.

Offers "Summary Report" feature which will indicate major problem in specific location.

Minimize wall space requirement

Accommodate up to 75 zones of 9 gasses each. Information base, 675 modules spread about several miles.

Amico Features

Individual Microprocessor for each display module.

Digital sensors can be mounted locally or remotely utilizing twisted pair wiring up to 5,000 ft. (1,524 m).

True digital LED readout with red "alarm", yellow each "caution" and green "normal" trend indicator for each service.

psi or kPa readout (switch selected).

Illuminated LED display readable even in poor smoked lighting conditions.

Self diagnostic and error message display for ease maintenance.

High / Low Alarm setpoints are field adjustable for each individual gas service.

Optional interface to the hospital Alarm Information Management System (AIMS).

Master Alarm modules can be intermixed with Area Alarm modules.

Repeat alarm, adjustable from 1 to 60 minutes, or off.

Dry contacts for remote monitoring of the high and low alarms.

Gas specific sensor with DISS nut and nipple. Display module, with an error message for incorrect sensor to display connection.

All modules are mounted on a hinged frame for easy accessibility.

Proposed System Features

Individual Microprocessor for each display and sensor and sensor module.

Digital sensors can be mounted locally or remotely utilizing twisted pair wiring up to several thousand feet via star configuration feature.

LED indication of "normal", "low", and "high" for area module.

psi or kPa readout (software selectable).

Four digit seven segment display enhanced by overlay for crisp viewing regardless of light or

Self configuring, and four digit text / acronym of message for quick response to error condition.

High / Low Alarm setpoints are field adjustable for individual gas service.

Optional communication interface to text messaging Master Module

One Master module should accommodate entire system

Repeat alarm adjustable in one minute increments. Default TBD.

Not required if communications options is utilized

Gas specific sensor, with on display gas identification.

All modules are mounted on a hinged frame for easy accessibility.

Each area alarm module only requires 4 square inches of wall space. Compared to 24 square inches.

Area Panel Identity location information entered at panel.

Additional area modules may be "hot" plugged into system.

Area module will display floor #, and room # of area fault.

Amico "System":

Microprocessor based alarm polling network.

Standard configuration will support 56 alarms.

Continuous scanning of all alarms.

Hospital alarm topology and clone image of any medical gas alarms in the hospital on a P.C.

Two wire twisted pair serial connection (up to 5,000 ft.)

Program can support printer for incident and trending, pager for unmanned times or speaker for audio reports.

Proposed "System":

Self configuring* no time consuming switch settings either for the sensor wiring or area panel wiring.

Star connection gives more wire pull flexibility when going from floor to floor.

Robust system error detection and recovery (noise immunity), and traffic management.

Summary mode* when multiple sensors out of range or off line, for quick troubleshooting and installation. (Every x alarm displays it would summarize the most frequent locations. For example a summary might be _FLOOR 3_ indicating many sensors are alarming on the third floor.)

System tolerant of power outages, reconfigures quickly after interruption.

Wire break detection, remainder of system functions normally.

Computer monitoring available, real time data on all sensors at a glance.

Long distance capability* up to 5000_ between area comms (x 75 = 71 miles!) with Star connections possible at ends. Facilitates multi-building campus systems.

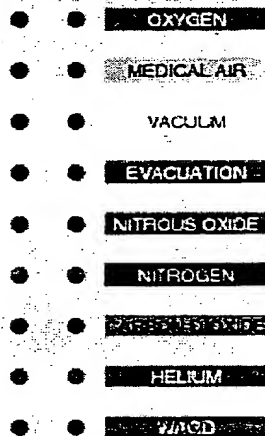
Sensor type not limited to gas pressure, may be any measurable quantity* including switch inputs. (With module modification.)

Alarms may be _locked out_* of systems with several master displays so areas uninvolved with an alarm are not annoyed. (Normal default is ALL masters alarm on ALL faults.)

New areas may be _hot plugged_* into the system without shutting everything down. (If you _hot UNplug_ however you will generate a wire fault, because the connection _went away_. Use the _system maintenance function_ to suspend wire fault alarms.)

Master Panel

Hill-Rom
A HILLENBRAND INDUSTRY



- Power
- Reserve Power

Push to
Test

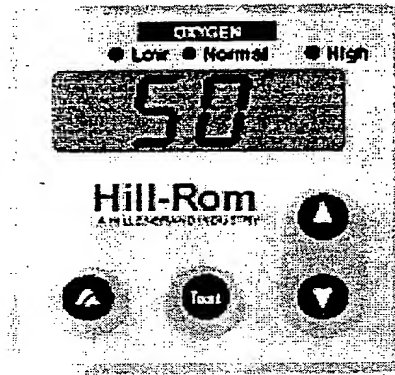
Alarm
Silence

0-0-0

Features & Capabilities:

- Accept up to 30 local signals
- Test key
- Alarm silence key
- Indicate local fault by LED, audible signal, and text message
- Indicate Area fault(s) by audible signal, and text message
- Communicate up to 75 area panels, total area display modules that may communicate to Master - 675
- Communicate to P.C., and building automation systems

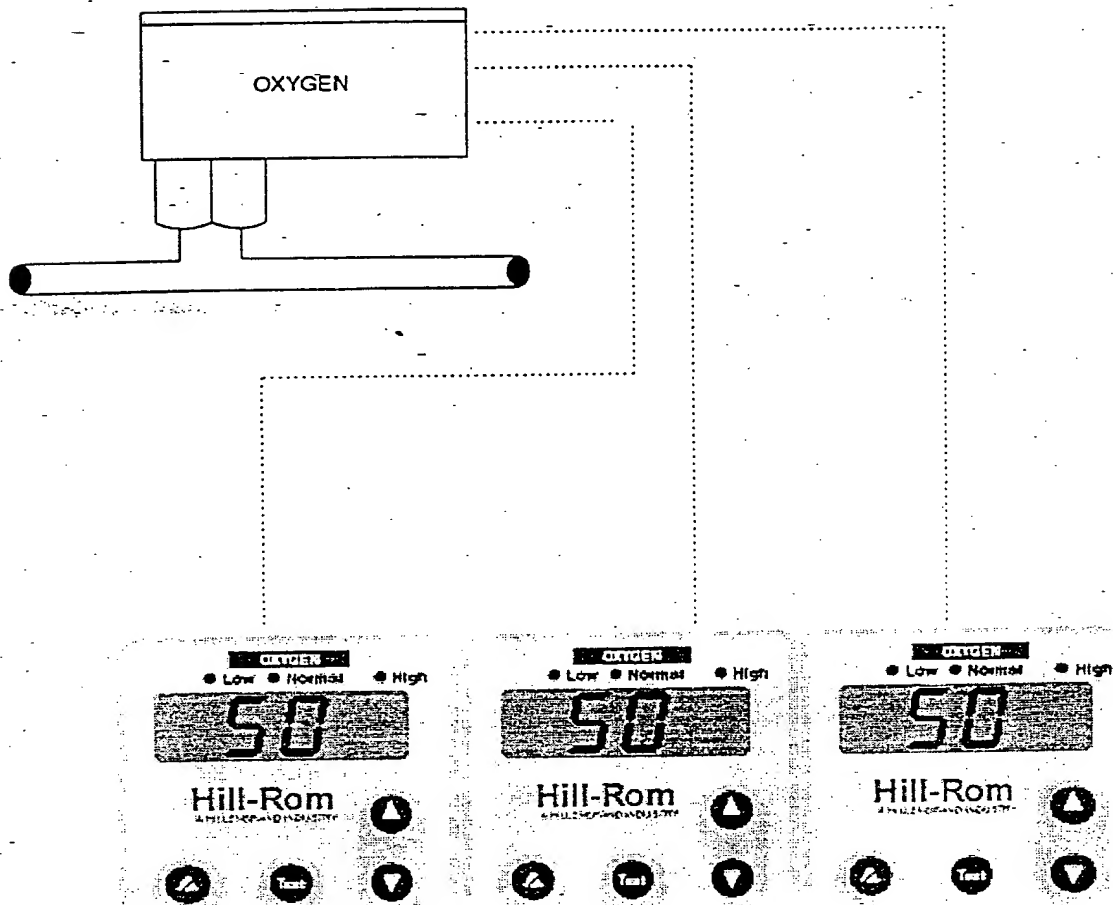
Area Display Module



Features & Capabilities:

- Self configuring - sensor I.D.
- LED's indicate Low, Normal, and High status
- Display shall flash actual pressure / vacuum when condition is other than normal
- Test key
- Alarm silence key
- Menu programmable;
 - Program floor #
 - Program room #
 - Program wing
 - Program limits
- Standard 1/16 DIN opening

Transducer



Features & Capabilities:

- One Transducer can communicate up to three Area Display Modules
- Communicate up to 5,000 ft. per line
- Each Transducer has individual I.D.

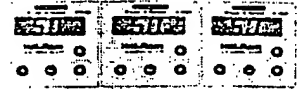
Floor 2

All Rooms equipped with O2, Air, Vac

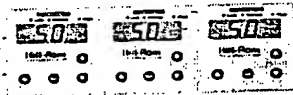
N.W. Wing



N.E. Wing



S.W. Wing



S.E. Wing



Floor 1

All Rooms equipped with O2, Air, Vac

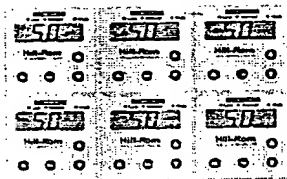
N.W. Wing



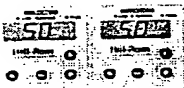
N.E. Wing



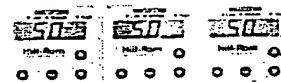
O.R.



E.R.



I.C.U.



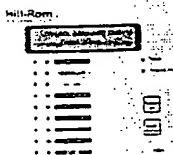
S.W. Wing



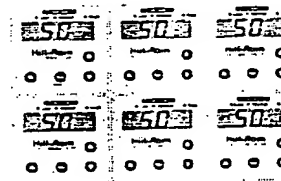
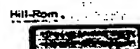
S.E. Wing



Engineering

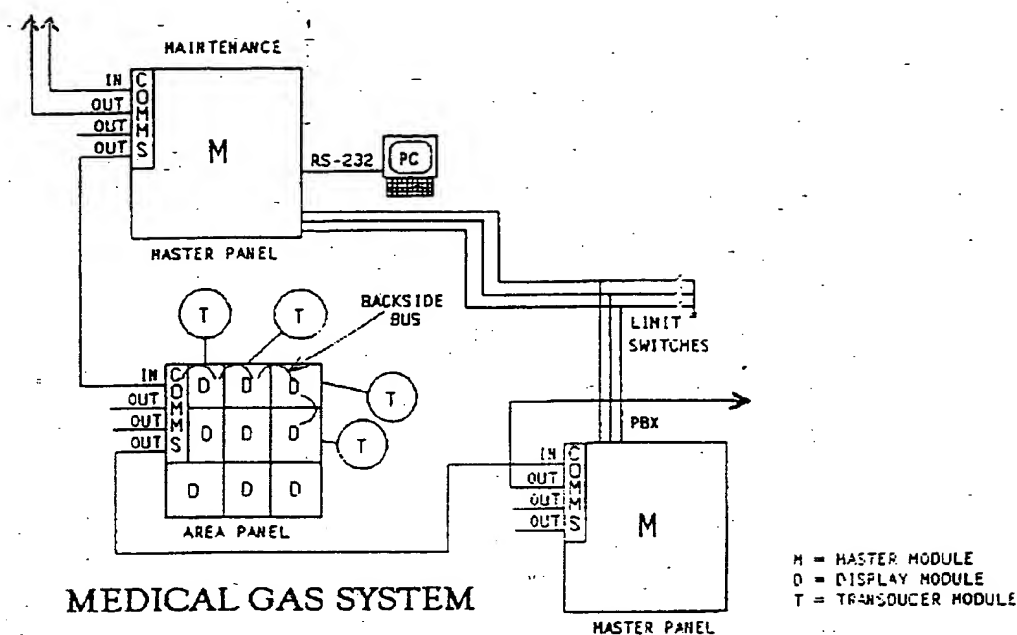


PBX



System Features:

- Flexible communication concept.
- Distance from Master up to several miles via twisted pair.
- Accommodates up to 75 different area display panels.
- Accommodates up to 675 area display modules.
- Self configuring - Masters supervise entire system local and area signals and faults.
- System Ready ? feature - allows contractor to switch out alarm circuitry during start up.
- Communicates to P.C. and Building automation Systems via RS 232.
- Easily adapts to additional sensor modules i.e. monitor pressure, temperature, flow, elapsed time, counts or rates, almost anything!
- System install requires less wall space
- New proprietary technology
- Possible to obtain System Design patent.



MEDICAL GAS SYSTEM

Area Comms Connects to other Area Comms in Area Panels or Master Modules (integrated Comms)

- Optically isolated to eliminate system problems
- Consists of one "IN" port and three "OUT" ports
- All ports communicate bi-directionally
- May be "Hot Plugged" to simplify maintenance and installation
- Communication on the "OUT" ports is controlled by the Comms Module
- Communications on the "IN" port is controlled by the "OUT" port of another Comms Module
- Each comms line may be up to 5000' #22AWG shielded twisted pair.
- Each Comms Module must be connected via "IN" from an "OUT". If further connections are desired they may be connected to the remaining "OUT" terminals.
- Redundant signaling may be created by parallel, or ring, connections

